K112967

PoliDent

AUG 28 2012

Polident d.o.o.
Dental Products Industry
Volčja Draga 42
5293 Volčja Draga
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Title 5: 510(k) Summary

510(k) owner`s name:	Polident d.o.o. Dental Products Industry Volčja Draga 42 5293 Volčja Draga Slovenija Phone: 00386-53304840 Fax: 00386-53304870
Contact person:	mag. Janja Lipušček Phone: 00386-53304859 e-mail: janja.lipuscek@polident.si
Date of summary:	27th August, 2012
Trade name:	**PMMA CAD/CAM DISC**
Classification name:	Temporary crown and bridge resin
Product code:	EBG
Regulation number:	872.3770
Device class:	II
Legally marked equivalent device:	ZENO PMMA disc
510(k) number:	K080182

Device description:
PMMA CAD/CAM discs are blanks used in different milling machines (dental CAD-CAM systems) by professional dental technicians.
They are composed of hot cured polymethyl methacrylate (PMMA) and pigments.
Device is available in A1, A2, A3, B1, B2, B3, BL3 and clear shades. Discs of all shades are available in different dimensions (diameter, thickness and profile margin).

Indications for Use:
- fabrication of temporary crowns and bridges.

Summary of the technological characteristics compared to the predicate device:
Polident PMMA CAD/CAM discs are substantially equivalent to the dental device ZENO PMMA disc.
The proposed and predicate devices are both composed of polymethyl metacrylate hot cured polymer and have similar indications for use. The proposed and predicate devices have similar physical and chemical properties. The polymerization grade of both devices is high. They have the same aesthetic function.
We can conclude that Polident PMMA CAD/CAM disc has comparible technological characteristics to the predicate device.

Substantial equivalence:
The proposed and predicate devices are both composed of polymethyl metacrylate hot cured polymer. Both devices have similar indications for use. The proposed and predicate devices have similar physical and chemical properties. Both devices have comparable e-modulus, flexural strength and deflection. The polymerization grade of both devices is high. They have the same aesthetic function.
Cytotoxicity, sensitization and irritaton testing was conducted on PMMA CAD/CAM discs.

Conclusion:
We are claiming substantial equivalence of PMMA CAD/CAM disc to the predicate device ZENO PMMA disc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Janja Lipušček
Polident d.o.o., Dental Products Industry
Volčja Draga 42
Volčja Draga
Slovenia 5293

AUG 28 2012

Re: K112967
Trade/Device Name: PMMA CAD/CAM disc
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: August 20, 2012
Received: August 23, 2012

Dear Ms. Lipuscek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony B. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Title 4: Indications for Use Statement

510(k) Number (if known): K112967

Device Name: **PMMA CAD/CAM disc**

Indications For Use:

- fabrication of temporary crowns and bridges

Prescription Use: ___X____ AND/OR Over-The-Counter Use:___/____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112967